

Blue Goat Cyber to Share Critical FDA Cybersecurity Strategies at AMDM 2025 Annual Meeting

Blue Goat Cyber will reveal critical FDA cybersecurity strategies for medical device manufacturers at AMDM 2025, helping accelerate regulatory success.

SCOTTSDALE, AZ, UNITED STATES, April 28, 2025 /EINPresswire.com/ -- Medical device manufacturers increasingly face regulatory setbacks, with cybersecurity deficiencies emerging as one of the top reasons for FDA premarket submission delays and rejections. At the 2025 Association of Medical Diagnostics Manufacturers (AMDM) Annual Meeting, Blue Goat Cyber will deliver essential strategies to help companies address these challenges and secure faster FDA approvals.



[Christian Espinosa](#), Founder and CEO of Blue Goat Cyber, will present "Cybersecurity & Lessons Learned from CDRH FDA Software Reviewers" on April 30, 2025, at 3:20 PM Eastern Time in Bethesda, Maryland. His session will guide regulatory, quality, and engineering leaders through critical insights into what FDA reviewers expect, highlighting the most common cybersecurity pitfalls that delay or derail submissions—and how to avoid them.

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Cybersecurity isn't optional anymore. If you treat it like an afterthought, the FDA will notice—and so will investors and patients counting on your device.”

Christian Espinosa, Blue Goat Cyber Founder and CEO

With cybersecurity gaps linked directly to patient safety risks, submission delays can stretch 6–18 months, costing manufacturers millions in lost market opportunity and

investment confidence. Through years of supporting medical device companies of all sizes, Blue Goat Cyber has developed a proven methodology for identifying and documenting cybersecurity risks early, aligning controls with FDA guidance, and building comprehensive cybersecurity documentation, including threat models, SBOMs, and real-world penetration testing results.

In his presentation, Espinosa will outline a practical three-step blueprint to help attendees integrate cybersecurity from the design phase onward, reducing regulatory risk and accelerating time-to-market. He will share case studies illustrating how early cybersecurity engagement preserves product features, avoids costly redesigns, and positions companies as leaders in a competitive MedTech landscape.

Blue Goat Cyber has helped hundreds of manufacturers achieve successful FDA cybersecurity evaluations, maintaining a 100% success rate. Their expertise spans simple to complex devices, including AI-enabled SaMD, wearables, IVDs, and critical care machines.

"Cybersecurity is no longer just a compliance requirement—it's a foundation for faster approvals, stronger patient safety, and greater investor confidence," said Espinosa.

The AMDM 2025 Annual Meeting will be held April 30–May 1, 2025, in Bethesda, Maryland. Full agenda and registration details are available at www.amdm.org/april-meetings.html.

For more information on how Blue Goat Cyber helps MedTech innovators accelerate regulatory success, visit <https://bluegoatcyber.com>.

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